UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
Office of Environmental Measurement and Evaluation
11 Technology Drive, North Chelmsford, MA 01863-2431

MEMORANDUM

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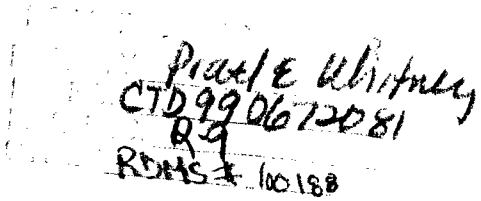
Date: April 17, 2003

Subject: QA review and comments
Voluntary Corrective Action Program
Pratt & Whitney Connecticut Facilities
East Hartford, CT
Prepared by LEA (Nov 1996)



From: Alan Peterson, QA Chemist

To: Juan Perez, EPA RCRA Project Manager

The Quality Assurance Unit has reviewed two documents related to the Pratt & Whitney Voluntary Corrective Action Program. The first document was the facility wide Quality Assurance Project Plan (QAPP), dated November 1996, and the second document was the Site Investigation Remediation Report for the North Parcel at the Airport/Klondike Area, dated July 28, 2000. The purpose of the review was to evaluate the documents relative to EPA's Quality Assurance requirements for the collection of environmental data. Below are our comments.

GENERAL COMMENTS

The QAPP LEA developed in 1996 was both a good product and a good approach to dealing with a very complex project. This document was set up as over-arching program QAPP, which laid out the quality assurance program that all the work would be conducted under, and provided an overview of the multiple facilities covered under the voluntary corrective action. For each Pratt & Whitney facility, the QAPP then broke out numerous Environmental Units (EUs) that would need to be investigated. The results of these individual EU investigations are then being documented, under separate cover, in Unit Specific Technical Memoranda (USTM).

In reviewing the above documentation, the Quality Assurance Unit finds two significant areas where the work being conducted at Pratt & Whitney departs from EPA quality assurance requirements. The two areas are 1) the lack of pre-planning documentation and 2) the lack of any validation of the data being received from the laboratory, as well as any overall assessment of the usability of the data. This information plays an important role in establishing a case for closure of the EU sites under investigation. These areas are discussed in further detail below, along with recommendations for handling future work.

1) **Pre-Planning Documentation**: EPA recommends that a systematic planning process be used to thoroughly plan out and document project tasks prior to performing the work. Information on EPA's systematic planning process can be found in *Guidance for the Data Quality Objectives Process* (QA/G-4), EPA/600/R-96/055, August 2000. This document can be downloaded from the web at: http://www.epa.gov/quality/qa_docs.html. The Data Quality Objective process helps determine the type, quantity, and quality of data that needs to be collected in order the meet the

goals and objectives of a project. Some of the primary information that is documented out of this process includes:

a) The current status of the particular EU(s) under investigation needs to be well defined (i.e., site background), including the problems to be solved and decisions to be made.
b) The objectives of the investigation at each EU needs to be summarized, including how the various tasks being performed are meant to address the problems and decisions defined in the site background.
c) The design concepts behind the proposed sampling plan needs to be detailed, including associated sampling tables and maps.

The documentation of these planning steps has not been performed by LEA (with regard to the North Parcel at the Airport/Klondike Area). Instead, LEA has jumped right to the USTM reports, presenting only limited planning information through hindsight discussion in the text. Note, this approach also appears to be contrary to that stated in the 1996 QAPP, which indicates that a preliminary qualitative risk assessment and sampling and analysis plan would be prepared as part of a modified RCRA Facility Investigation at each EU.

By preparing these plans (detailing problems, objectives and rationale behind sampling design), you provide EPA with an understanding of the thought process that was behind the work being performed, and give the reviewer a reference point on which to evaluate the data against. The USTMs presented by LEA simply state what was done and what was detected, and do not the provide the reviewer with any sense of context for the objectives and designs behind the work. This hinders EPA's ability to evaluate the data and make decisions based on the results.

EPA recommends that all future work conducted at Pratt & Whitney facilities be performed according to approved Sampling and Analysis Plans (SAPs) under Pratt & Whitney's Program QAPP. These SAPs are to be prepared and approved prior to performing the work. (Note, in the voluntary corrective action program, signed approval of the plans would be performed by Pratt & Whitney and LEA project managers to signify concurrence on the work to be performed.) An example of the recommended information to be provided in a SAP is included at the end of this memorandum.

In essence, the SAPs become addendums to the Program QAPP, and the USTMs become the investigation report that is paired with the individual SAPs. Using the the QA concept of "Plan - Do - Check", the USTM report then provides the check on the implementation of the plan. A typical USTM report might include: 1) a summary of the field activities that took place, including any significant observations recorded in the field, and any modifications or changes to the proposed plan that was presented in the SAP, 2) the results and observations obtained from the data (text, tables, charts, maps, etc.), 3) a QA/QC assessment of the data (see comment 2 below), and 4) conclusions about the project, including any trends, anomalies, or gaps in the data that were observed, and a discussion of any limitations on the way the data is to be used or interpreted by the data user.

2) **Data Validation and Usability**: Data Validation and Usability is the last major group of elements described in *EPA Requirements for Quality Assurance Project Plans* (QA/R-5), EPA/240/B-01/003, March 2001. (Note, this EPA document can be also be found at the above listed website.) These elements relate to the closure of a project from a QA standpoint. They involve an independent assessment of the data generated in the field and by the contracted laboratories. This step has not been performed on any of the data presented in the USTMs for the Airport/Klondike Area. Rather, LEA has used the data directly (as provided by the laboratory), with no independent assessment of its quality. Although the laboratories do provide

some level of data review prior to submitting the report, EPA considers the prime contractor responsible for the quality of that data, and as such, requires that a review, independent of the laboratory generating the data, be performed.

Thus, it is recommended that a Data Validation and Usability assessment plan be developed and implemented for all future environmental data collection projects performed at the Pratt & Whitney facilities. Below is a general concept for what this type of assessment will involve. The QA Unit would be glad to work with Pratt and Whitney on customizing a Data Validation and Usability assessment plan that meets their needs:

a) Step 1 - Data Verification: This step involves the gathering of all the field and laboratory data into an organized project file, and reviewing it for completeness, compliance, and correctness. That is, check that all the data there, that what is there is what was agreed upon in the QAPP (i.e., deliverable requirements, right methods, etc.), and that there are no typographical errors that need to be corrected. The QAPP should list all the types of data to be collected, discuss the organization and review process, indicate who is responsible for this task, and indicate what documentation of this task is to be provided in the final report (e.g., attached signed checklist of data compiled, with notes on any observations or changes made).

b) Step 2 - Data Validation: This step involves 1) a more in-depth review of the field data, and 2) an evaluation of the analytical data. Depending on the use of the data, different levels and amounts of data evaluation may be employed.

   1) Performance Evaluation (PE) sample: A blind PE sample is submitted to the laboratory which contains the contaminants of concern for the site under investigation. The laboratory results for the PE sample are evaluated against the known concentration and control limits for the PE sample, and the results reported, including a discussion of any limitations of the use of the data based on those results.
   2) Includes item 1 above, plus an evaluation of the QC data analyzed with the field samples: The results of the QC data are compared to the individual control limits, and the data is qualified (acceptable, estimated or rejected) based on those results, including a discussion of any limitations of the use of the data based on the findings. Types of QC data include: preservation and holding times, calibration data, blank data, laboratory control samples, laboratory duplicates, matrix spike data, etc. The QAPP should
   3) Includes items 1 and 2 above, plus evaluation of all the raw data: This includes and evaluation of all the instrument printouts, recalculation of field sample results, etc. Again, the results of this evaluation are used to qualify the data, including a discussion of any limitations of the use of the data based on the findings.

   The program QAPP should document the Data Validation plan that will be routinely performed on data collected at EU investigations.

c) Step 3 - Data Usability Assessment: This assessment is also called "Reconciliation with User Requirements". That is, the data is evaluated against the user requirements specified in the QAPP for precision, accuracy (and bias), representativeness, completeness, comparability, and sensitivity. In addition, the sampling design for the project is evaluated to determine if it met the goals for the project. Based on the documents results of these assessments, a discussion of the overall success of the project

is presented, along with any trends, anomalies or gaps in the data, including any limitations on the way the data should be used or interpreted by the data user. The program QAPP should document how these steps will be performed, who is responsible for performing the usability assessment, and where the results of this assessment will be documented.

3) **Summary**: Currently the program QAPP for the Pratt and Whitney Voluntary Corrective Action is over 5-years old. EPA limits the period of applicability of QAPPs to up to 5-years. After that time, the QAPP must be updated and/or revised as appropriate, and reissued for review and approval. This being the case, EPA highly recommends that LEA revise and reissue the Pratt & Whitney program QAPP, and in so doing, address the above noted QA issues. By doing this, Pratt & Whitney will be in a better position to obtain closure on the work they are conducting under to voluntary corrective action program. Note, the EPA QA Unit would like to request that LEA consider submitting the revised QAPP to EPA for review and comment.

Should you have any questions concerning this review, please feel free to contact me at 617-918-8322.

Sampling and Analysis Plan

The following is a example of what should be included in an EU specific SAP (Note, these are all elements of EPA's QA/R-5, *EPA Requirements for Quality Assurance Project Plans*.

1) Section A1 - Title and Approval Page: (Pratt & Whitney and LEA concurrence. EPA approval if desired)

2) Section A2 - Table of Contents:

3) Section A3 - Distribution List: (for the particular site work being conducted)

4) Section A4 - Project Organization: (for the particular site work being conducted)

5) Section A5 - Problem Definition/Background: Please describe the site history/background that has led up to the objectives of the current project. Identify particular contaminants of concern and the magnitude of contamination present, if known. If the SAP is addressing additional sampling (i.e., the initial phase of sampling you conducted showed that further sampling was required), the this section would now describe the events that led to the need for additional sampling. Note, clarify the problems to be solved and/or the decisions to be made.

6) Section A6 - Project/Task Description: Describe the objectives of the work to be conducted and summarize the tasks to be performed. Indicate how the tasks relate to and are intended to address the problems/decisions to be resolved. In addition, please include:

    1) Project Schedule: Include/update as appropriate.
    2) Report(s): Please outline the report deliverables that will be generated based on the addendum.

7) Section B1 - Sampling Design: Describe the specific details of the project tasks to be performed. Include in that, a discussion of the thinking behind the logic and rationale used to choose the individual sampling locations, the analyses to be performed, and any unified rationale for the layout of the sample locations as a whole. In addition, please include:

    1) Site Sampling Map(s): Please include/update the site map(s) with the currently proposed sampling locations.
    2) Sampling and Analytical Summary Table(s): Please provide sampling and analytical summary table that includes:
        1) Matrix
        2) Analytical parameter
        3) Extraction and Analytical Method references
        4) Sampling Method reference
        5) Number of field sample
        6) Type and number of each field QC sample collected for each matrix and parameter
        7) Sample containers, sample preservation, and sample holding times.

8) Section B2 - Sampling Methods: Please list the individual sampling SOPs that will be used in performing the SAP addendum work. Note, if there are any changes or modifications to these SOPs, those changes should be documented in the QAPP addendum. Also, if any new sampling procedures (not present in the original program QAPP) are to be used, then those SOPs should be included with the SAP addendum, for transfer into the program QAPP.

9) Section B4 - Analytical Methods: Please list the individual analytical SOPs that will be used in performing the SAP addendum work. Note, if there are any changes or modifications to these SOPs, those changes should be documented in the QAPP addendum. Also, if any new analytical methods (not present in the original program QAPP) are to be used, then those SOPs should be included with the SAP addendum for transfer into the program QAPP.

10) Reference to Original QAPP: Please provide a complete reference to program QAPP in the introduction to each of the SAP addendums. The reference should indicate that the remaining QAPP elements (not covered in the SAP addendum) will be performed in accordance with the original program QAPP.